Premarket Notification (510(k)) Summary

MAR 1 8 2013

3M

510(k) Number: **K123546**

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Suzanne Leung, Ph.D., RAC
Regulatory Affairs
Phone Number: (651) 575-8052
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Date of Summary: March 14, 2013

Device Name and Classification:

Common or Usual Name: Reader/Incubator

Proprietary Name: 3M Attest™ 390 Auto-reader
3M Attest™ 390G Auto-reader

Classification Name: Accessory to Biological Sterilization Process Indicator
(21 CFR § 880.2800(a))

Product Class: Class II

Product Code: Accessory to FRC

Predicate Devices:

Product Name	'Primary Predicate'	'Design Predicate'
Attest™ 390 Auto-reader	Same Intended Use and Indications for Use as Attest™ 290 Auto-reader (K004009)	Similar in design to Attest™ 490 Auto-reader (K103277, K121484)
Attest™ 390G Auto-reader	Same Intended Use and Indications for Use as Attest™ 290G Auto-reader (K031012)	Similar in design to Attest™ 490 Auto-reader (K103277, K121484)

Description of Device:

The Attest™ 390 and 390G Auto-readers are used in conjunction with Attest™ Rapid Readout Biological Indicators by trained personnel in central sterilization departments to monitor sterilization processes. The 390 and 390G Auto-readers, like its predecessors the Attest™ 290, 290G and 490 Auto-readers, have two functions. First, the devices serve to incubate the biological indicator (BI) at the temperature appropriate to the organism. Second, the devices determine whether a potential sterilization failure may have occurred by measuring the intensity of fluorescence produced by an enzymatic reaction associated with spore growth inside the self-contained biological indicator.

The 390 and 390G Auto-readers include a Crusher Well in which the Attest™ Rapid Readout biological indicators are activated. After activation, the user places the biological indicator into one of the 10 color-coded Incubation Wells. The 390 and 390G Auto-readers have an incubation block controlled to the appropriate temperature for their respective biological indicators. The Auto-readers contain a LCD panel that shows the time remaining for incubation. Fluorescence detection at each incubation well is accomplished by the use of a UV LED and a photo diode sensor. As soon as a positive result is detected, a '+' sign is shown as an indication of sterilization cycle failure, accompanied by an audible alarm. At the end of the specified incubation time, if a negative result is detected, a '-' sign is shown on the LCD panel as indication of an adequate sterilization cycle. When the test is complete, as indicated by the (+) or (-) symbol on the Auto-reader LCD panel under the incubating BI, the customer records the result and disposes of the biological indicator.

390 Auto-reader

The 3M Attest™ 390 Auto-reader is an accessory to the 3M Attest™ Rapid Readout self-contained biological indicators 1291 and 1292 that are designed to incubate at 60°C. The 390 Auto-reader incubates and automatically reads the Attest™ 1291 and 1292 biological indicators for a fluorescent result within 1 hour for 1291 and 3 hours for 1292.

The 390 Auto-reader can be configured for three different configurations of biological indicators. The first configuration allows the 390 Auto-reader to read 1291 biological indicators in all 10 wells. The second configuration allows the 390 Auto-reader to read 1292 biological indicators in all 10 ten wells. The third configuration allows the 390 Auto-reader to read 1291 biological indicators in the 5 wells to the left and 1292 biological indicators in the 5 wells to the right. The user inserts the biological indicator into the well with the matching color to the biological indicator's cap (blue cap 1291 into blue well, brown cap 1292 goes into brown well).

390G Auto-reader

The 3M Attest™ 390G Auto-reader is an accessory to the 3M Attest™ Rapid Readout self-contained biological indicator 1294 that is designed to incubate at 37°C. The 390G Auto-reader incubates and automatically reads the Attest™ 1294 biological indicator for a fluorescent result within 4 hours. The incubation wells are color coded green to match the cap of the 1294 biological indicator.

Indications for Use:

The 3M Attest™ 390 Auto-reader is designed to incubate and automatically read the 3M Attest™ Rapid Readout Biological Indicators for Steam, 1291 and 1292, at 60°C for a final fluorescent result at 1 hour for 1291 and 3 hours for 1292.

The 3M Attest™ 390G Auto-reader is designed to incubate and automatically read the 3M Attest™ Rapid Readout Biological Indicator for Ethylene Oxide, 1294, at 37°C for a final fluorescent result at 4 hours.

Comparison of the Attest™ 390 and 390G Auto-readers to their Predicate Devices:

Intended Use and Indications for Use

All of the Auto-readers share the same Intended Use. These devices incubate the biological indicators (BIs) to determine a positive or negative result based on a fluorescence signal. An increase in fluorescence signal, created by spore germination, indicates a failed sterilization cycle.

The Indications for Use for the 390 Auto-reader is the same as the predicate 290 Auto-reader, to incubate and automatically read Attest™ 1291 and 1292 biological indicators. The Indications for Use for the 390G Auto-reader is the same as the predicate 290G Auto-reader, to incubate and automatically read the Attest™ 1294 biological indicator.

Incubation Temperature

The 390 Auto-reader reaches an incubation temperature of 60+/-2°C within 30 minutes of power up at room temperature and maintains its temperature throughout the incubation period at labeled environmental conditions (16-40°C, 20-80% RH, non-condensing). The predicate device, the Attest 290 Auto-reader, has the same incubation temperature specifications.

The 390G Auto-reader reaches an incubation temperature of 37+/-2°C within 30 minutes of power up at room temperature and maintains its temperature throughout the incubation period at labeled environmental conditions (16-29°C, 20-80% RH, non-condensing). The predicate device, the Attest 290G Auto-reader, has the same incubation temperature specifications.

Basis of Rapid Readout

The Attest 390/390G Auto-readers and their predicate devices, the Attest 290/290G and 490 Auto-readers, all have Rapid Readout capabilities due to photodiodes that detect fluorescence produced by enzymatic activity that results from growing biological indicator organisms.

Voltage Range

All Auto-readers share the same voltage range, operating at 100-240 Volts AC with a 12 Volt DC conversion for internal circuitry.

Visual Display and Audible Alert Tone

The Attest 390/390G Auto-readers contain an update to the visual display from the 290/290G Auto-readers. Like the 'design predicate' the 490 Auto-reader, the 390/390G Auto-readers contain a LCD panel, which provides feedback to the user for each BI inserted into an incubator/reader well and displays a constant readout of time remaining for each BI. In contrast, the predicate 290/290G Auto-readers contain LEDs located at each well to indicate passed, failed, or in-process status to the user for each BI. All Auto-readers contain an audible alert tone that beeps to notify the user when a positive result has been detected.

PC Connectivity

The 390/390G Auto-readers can be connected to a PC via an ethernet connection to allow the user to view current status of BIs, view the last 100 BI results, and save documentation as a PDF file if desired. This is an option that also exists on the 490 Auto-reader but that the 290/290G Auto-readers do not have.

Summary of Predicate Comparisons

The 390 and 390G Auto-readers share the same Intended Use, Indications for Use, and fundamental scientific technology such as Rapid Readout capability and energy source as the predicate devices the 290 and 290G Auto-readers. Additionally, the 390 and 390G Auto-readers share updated design features with the 'design predicate' the 490 Auto-reader by providing a LCD panel and PC connectivity.

Evaluation Data for Determining Substantial Equivalence:

Biological Indicator Qualification

The validation of the 390 and 390G Auto-readers for use with their respective biological indicators was conducted following the FDA *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007. Multiple lots of 3M Attest™ Rapid Readout biological indicators were evaluated for performance when used with the 3M Attest™ 390 and 390G Auto-readers. A Summary of biological indicator testing is shown below.

Summary of Biological Indicator Qualification

Auto-reader	Testing	Acceptance Criteria	Result
390	Qualification testing with Attest™ 1291 BI	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout time • Fluorescent result in 1 hour	Pass
		Survival/Kill: All BIs survive after exposure at the survival time and all BIs are killed after exposure at the kill time	Pass
	Qualification testing with Attest™ 1292 BI	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout time • Fluorescent result in 3 hours	Pass
		Survival/Kill: All BIs survive after exposure at the survival time and all BIs are killed after exposure at the kill time	Pass
	Auto-reader Maintenance of Incubation Temperature	Maintain 60+/- 2°C over the specified incubation period	Pass
390G	Qualification testing with Attest™ 1294 BI	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout time • Fluorescent result in 4 hours	Pass
		Survival/Kill: All BIs survive after exposure at the survival time and all BIs are killed after exposure at the kill time	Pass
	Auto-reader Maintenance of Incubation Temperature	Maintain 37+/- 2°C over the specified incubation period	Pass

The results of these evaluations showed that the new Attest™ 390 and 390G Auto-readers are qualified for use with the Attest™ Rapid Readout biological indicators.

Electrical Safety and EMC Testing

The Attest™ 390 and 390G Auto-readers were also tested for safety by Underwriters Laboratory to verify compliance to:

- *IEC 61010-1 (2001) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements,*
- *IEC 61010-2-010 (2003) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

In addition, the Attest™ 390 and 390G Auto-readers have been tested by a certified Testing Laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations (2009) for:
  - Radiated Emissions (FCC Part 15, Subpart B, Class A)
  - Conducted Emissions (FCC Part 15, Subpart B, Class A), and
- IEC 61326: *Electrical Equipment for Measurement, Control and Laboratory Use—EMC Requirements.*

Substantial Equivalence Conclusions:

The Attest 390/390G Auto-readers are substantially equivalent to the Attest 290/290G Auto-readers, which share the same Intended Use and same Indications for Use. Both systems use the same fundamental scientific technology to incubate biological indicators and detect a failure in a sterilization cycle. They both provide the results to the user through a visual display and an audible alarm. Data has been generated that qualifies the 390/390G Auto-readers for use with the Attest Rapid Readout biological indicators and data has been generated that demonstrates compliance to electrical safety and EMC standards. The minor updates in design features provided with the 390/390G Auto-readers do not present any new questions of safety and effectiveness with the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Suzanne Leung, Ph.D., RAC
Regulatory Affairs
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3M Center, Building 275-5W-06
ST. PAUL MN 55144-1000

Re: K123546
Trade/Device Name: 3M Attest™ 390 Auto-reader and 3M Attest™ 390G Auto-reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: February 6, 2013
Received: February 8, 2013

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

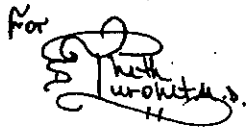
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Enclosure

Indications for Use Statement

510(k) Number: K123546

Device Name: 3M Attest™ 390 Auto-reader and 3M Attest™ 390G Auto-reader

Indications for Use:

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The 3M Attest™ 390G Auto-reader is designed to incubate and automatically read the 3M Attest™ Rapid Readout Biological Indicator for Ethylene Oxide, 1294, at 37°C for a final fluorescent result at 4 hours.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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